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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/883,249	06/19/2001	Arvydas Janulaitis	P 0281177 203472/JND/SV	9549
909	7590	12/24/2003	EXAMINER	
PILLSBURY WINTHROP, LLP			PATTERSON, CHARLES L JR	
P.O. BOX 10500			ART UNIT	
MCLEAN, VA 22102			PAPER NUMBER	

1652

DATE MAILED: 12/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/883,249

Applicant(s)

JANULAITIS ET AL.

Examiner

Charles L. Patterson, Jr.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 6/19/01, 3/3/03, 10/27/03.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10-13 and 15-29 is/are rejected.
- 7) ☒ Claim(s) 9 and 14 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 June 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The term "nuclease" is not descriptive of the claimed invention but is rather much too broad.

After consideration of applicants traverse of the restriction requirement and reading the instant application, the traversal is agreed with. All claims will be examined.

The disclosure is objected to because of the following informalities:

On page 18, four lines from the bottom, "Figure 3, lane 1" is referred to. Figure 3 does not contain lanes but rather a plasmid. Perhaps Figure 10 was intended.

Appropriate correction is required.

Claims 16 and 23-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 16 is confusing in the recitation of "activity 10of" on line 1.

Claim 23 is indefinite in the recitation of "[u]se according to claim 19". Claim 19 is drawn to a method, not a use.

Claim 24 is confusing and indefinite in the recitation of "first nickase as defined in claim 1 and "second nickase as defined in claim 1". Claim 1 does not define a first and second nickase but rather a first and second subunit. The claim is also confusing in the recitation of "the first nickase is capable of cleaving a first strand of the DNA duplex and the second nick-

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ase is capable of cleaving a second strand of the DNA duplex". The second subunit of claim 1 is incapable of cleaving the other strand of DNA.

Claim 25 is confusing and indefinite in the recitation of "first and second nickases". As stated *supra*, claim 1 does not refer to two nickases.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 23 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Use claims are not allowed in U.S. patent practice. The claim should be expressed as a method with definite steps.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-8, 10-13 and 15-29 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for endonuclease *Bpu10I*, does not reasonably provide enablement for claims of the scope of the instant claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to the invention commensurate in scope with these claims.

The specification teaches that restriction endonuclease *Bpu10I* has two subunits that are both necessary for cleavage of DNA to occur. It further teaches that when certain mutations are introduced into one of the subunits,

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the enzyme will cleave one strand but not the other strand of duplex DNA. Stankevicius, et al. (QR) teaches that "[t]his heterosubunit structure distinguishes Bpu10I restriction endonuclease from all other type II restriction enzymes described previously" (abstract). It is maintained that there may not be any other enzymes that have these characteristics, and even if there are these other enzymes might not be affected in the same way to mutation, i.e. the mutants will cleave one strand of duplex DNA but not the other. Therefore it is maintained that the claims should be limited to this endonuclease.

The examiner has been unable to find any prior art that would anticipate or make obvious the instant claims. Kong, et al (A), Kuhn, et al. (U) and Xu, et al. (V) are cited as of interest as they teach methods of making nickases from restriction endonucleases but they do not have priority over the effective filing date of this application and/or they do not use the method taught in the instant specification.

Claims 9 and 14 are objected to as being dependent upon a rejected base claim.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles L. Patterson, Jr., PhD, whose telephone number is 703-308-1834. The examiner can normally be reached on Monday - Friday, 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 703-308-3804. The fax phone number is 703-308-4242.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Charles L. Patterson, Jr.
Primary Examiner
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Patterson
December 19, 2003